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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,613	11/14/2001	Pramod K. Srivastava	8449-183-999	9970

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EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,613	SRIVASTAVA, PRAMOD K.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,19-22,24,25,27,28,30-36,39-42,45-48,51-54,57,58,60,61,63-66,68,69,71,72,74-80,83-86,89-92,95-98,101,102,104,105,108 and 110-139.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,19-22,24,25,27,28,30-36,39-42,45-48,51-54,57,58,60,61,63-66,68,69,71,72,74-80,83-86,89-92,95-98,101,102,104,105,108 and 110-139.

DETAILED ACTION

RE: Srivastava

Election/Restrictions

1. Upon further review and reconsideration, the restriction requirement mailed 3/24/2005 is hereby vacated in view of the newly amended and added claims, as such a new restriction requirement is set forth herein.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 31, drawn to a method of eliciting an immune response against a tumor comprising the administration of a population of purified stress protein-peptide complexes, wherein said complex is a combination of two or more HSP70-peptide complexes, HSP90-peptide complexes, and gp96-peptide complexes, classified in class 424, subclass 277.1.

II. Claims 19,21,33-36,39-42,57-58,63,65,77-80,83-86,101-102,111-125, and 132, drawn to an immunogenic populations of purified human stress protein-peptide complexes or a composition comprising human stress protein-peptide complexes, wherein said complexes comprise gp96, classified in class 530, subclass 402.

III. Claims 20, 64, 111-118, and 126-133, drawn to an immunogenic populations of purified human stress protein-peptide complexes or a composition comprising human stress protein-peptide complexes, wherein said complexes comprise a combination of two or more HSP70-peptide

complexes, HSP90-peptide complexes, and gp96-peptide complexes, classified in class 435, subclass 174.

IV. Claims 22,24-28,30-32,45-48,51-54,60-61,66-69,71-72,74-76,89-92,95-98,104-105,108-110, drawn to a method of treating a human with a tumor comprising administering to the human a composition comprising a purified gp96-peptide complex, classified in class 514, subclass 2.

V. Claims 134,136, and 138-139, drawn to a method of making an immunogenic population of purified human stress protein-peptide complexes, wherein the complexes are gp96-peptide complexes, classified in class 530, subclass 412.

VI. Claims 135,137, and 139, drawn to a method of making an immunogenic population of purified human stress protein-peptide complexes, wherein the complexes are a combination of Hsp70-peptide complexes, Hsp90-peptide complexes, and gp96-peptide complexes, classified in class 435, subclass 70.1.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of eliciting an immune response comprising the administration of a combination of HSPs (group I), a method of eliciting an immune response comprising

the administration of gp-96 (group IV), a method of making an immunogenic population of stress protein complexes, wherein the complex is a gp96-peptide complex (group V), and a method of making an immunogenic population of stress proteins complexes, wherein the complex is a combination of HSPs-peptide complexes (group VI) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for diagnosis of the autoimmune disease differ significantly for each of the materials. For eliciting an immune response, either a single (group I) or combination (group IV) of stress proteins are used. For making, stress-protein complexes either comprise a single stress protein (group V) or a combination of stress proteins (group VI). Therefore, each method is divergent in materials and steps. For these reasons the Inventions I, and IV-VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I, and IV-VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IV, and V-VI together.

5. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are structurally and functionally distinct.

The composition of group II and group III are patentably distinct for the following reasons:

While the inventions of both group II and group III are polypeptides, in this instance the polypeptide of group II is a single stress protein-complex, whereas the polypeptide of group III encompasses a combination of stress protein complexes. Thus the compostions of group II and the group III are structurally distinct molecules; any relationship between a compositions of group II and of group III is dependent upon the correlation between the scope of the polypeptides that make up the complexes.

Furthermore, searching the inventions of group II and group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications.

6. Inventions II & III and IV & I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to generate antibodies that bind to the stress protein-peptide complex.

Searching the inventions of Groups II and IV or III and I together would impose serious search burden. The inventions of Groups II and IV or III and I have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the complexes and the method of using the complexes are not coextensive. Group II and III encompasses molecules which are claimed in terms of

amino acid sequence and protein complex, which are not solely required for the search of Group IV and I. In contrast, the search for group IV and I would require a text search for the method of eliciting an immune response in addition to an amino acid search of the protein complex. Moreover, even if the composition were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

7. Inventions V & II and VI & III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made in vitro through artificial means, wherein the HSP can be complexes to artificial peptides with know antigenicities.

Searching the inventions of Groups V and II or VI and III together would impose serious search burden. The inventions of Groups V and II or VI and III have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the complexes and the method of making the complexes are not coextensive. Group II and III encompasses molecules which are claimed in terms of amino acid sequence and protein complex, which are not solely required for the search of Group IV and I. In contrast, the search for group V and VI would require a text search for the method of making the complex in addition to an amino acid search of the protein complex. Moreover, even if the composition were known, the method of making the product may be novel and unobvious in view of the preamble or active steps.

8. Claims 131 and 132 are generic to a plurality of disclosed patentably distinct species comprising cytokines. Applicant is required under 35 U.S.C. 121 to elect a **single** disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be

fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1643
September 16, 2005

CHRISTOPHER YAEN
PATENT EXAMINER